UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,752	03/09/2001	Gerhard Schmidmaier	8932-148	8071

20582 7590 03/31/2004

JONES DAY
51 Louisiana Aveue, N.W
WASHINGTON, DC 20001-2113

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,752	SCHMIDMAIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *32-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2004/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response/Remarks and the Amendment, both filed 09/29/03, the Information Disclosure Statement (IDS) filed 11/06/03 and the Foreign Priority Papers filed 12/18/03 is acknowledged.

Newly submitted claims 32-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original invention claims an implant comprising a varnish-like biodegradable polymer coating wherein the biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo. Newly presented claims 32-59 claim an orthopedic implant having a fixed contour for placement adjacent bone, the implant comprising a metallic body that defines a periphery and an abrasion resistant biodegradable polymer deposition on the periphery. The inventions are entirely distinct in the features recited.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-59 have been *withdrawn* from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The 35 U.S.C. §112, second paragraph rejections and the 35 U.S.C. §102(b) rejections have been *withdrawn.*

Claims 1-31 are pending. Claims 1, 21 and 31 have been amended. Claims 1-31 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7-19 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arm et al. (WO 93/20859).

Arm et al. teach implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

According to Arm, degradation of the film and consequent release of growth factors there from can be modulated by adjusting such film parameters as molecular weight, copolymer structure, copolymer ratio and thickness. In general, the film will be

formulated using a copolymer having a molecular weight between 10,000 and 200,000 Daltons. Film thicknesses of less than about 50 microns are preferred. Figure 1 illustrates a 40-50 micron film of PLA/PGA random copolymer of approximately 100,000 molecular weight (page 6, line 28 through page 7, line 5).

Suitable polypeptide growth factors include PDGF, TGF-alpha, TGF-beta, IGF-I, bFGF, aFGF, EGF and the like. Growth factors may be used singly or in combination with one another (page 7, line 6-17). Suitable biodegradable polyester films include polylactic acid, polyglycolic acid, polydioxanone or polylactic acid/polyglycolic acid copolymer films (page 5, lines 10-19).

In addition to the copolymers, growth factors and carriers, the biodegradable films may include other active or inert components. Of particular interest are those agents that promote tissue growth or infiltration. Agents that promote bone growth, such as morphogenic proteins, osteogenin and NaF, for example can be included (page 11, line 32 through page 12, line 4).

Regarding the amount of polymer employed per ml of solvent, Arm in Example 1, page 15, demonstrates the teaching of polylactic acid and polylactic acid-polyglycolic acid films that were solvent cast by dissolving approximately 340 mg of polymer granules in 10 ml of chloroform at room temperature and allowing the solvent to evaporate completely in an air hood.

With respect to the instant percentages (0.1-10%) and instant combinations of growth factor, it appears that the amounts taught by Arm (0.0375 and 1.5 micrograms per mg of copolymer – pg 12, lines 13-24) fall within the applicant's claimed ranges.

Furthermore, one of ordinary skill in the art could determine suitable ranges through routine or manipulative experimentation to obtain the best possible results. There is no criticality seen in the amounts of growth factor employed since Arm explicitly teaches similar amounts for a similarly intended purpose. Furthermore, there is no criticality seen in the particular combination of growth factors, since Arm clearly suggests at page 7, lines 8-10, that the growth factors may be used singly or in combination. One of ordinary skill would select a suitable growth factor or a combination of growth factors, based on the intended purpose at hand.

Claims 1, 2, 4, 5, 8-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller *et al.* (US Pat. No. 4,610,692).

Eitenmuller et al. teach an implant for filling bone cavities and fixing bone fragments in a living body comprising at least one coating of predetermined thickness, about 4 microns to about 30 microns, of a biodegradable substance selected from at least one of polymethacrylate, polylactide, polydextran and cellulose-based substances, wherein the implant also comprises at least one therapeutically active ingredient (see reference column 3, line 10 through col. 4, line 36); (col. 6, lines 14-25); (col. 7, lines 23-44); and claims.

Claims 1-6, 8-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy *et al.* (US Pat. No. 5,670,161).

Healy teach an expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and caprolactone, wherein the stent incorporates surface coatings or thin films having a thickness of about 25 microns and whereby suitable polymers include polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, polymethacrylic acid and polyacrylamide that are blended and copolymerized with biodegradable materials. The film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The stent may also desirably incorporate one or more drugs, growth factors and inhibitors (see reference column 5, lines 27-60); (col. 10, lines 10-48); and claims.

Response to Arguments

Applicant's arguments filed 09/29/03 have been fully considered and are persuasive regarding the 35 U.S.C. §112 second paragraph rejections. Accordingly, the 112, second paragraph rejections for claims 1, 4, 5, 10 and 31 have been withdrawn.

Secondly, the Applicant argues regarding the 35 U.S.C. §102(b) rejections of claims 1-5, 7-12, 16, 17, 21-23 and 29-31 over Arm et al. (WO 93/20859), the §102(b) rejection of claims 1, 2, 4, 5, 8-10 and 20 over Eitenmuller et al. and the §102(b) rejection of claims 1-6, 8-12 and 20 over Healy et al., stating, "Arm does not disclose,

teach or suggest an implant having a "varnish-like" coating; Eitenmuller does not disclose an implant wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo and Healy does not disclose an implant wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo."

Applicant's arguments with respect to the above noted claims have been considered but are moot in view of the new position taken by the Examiner.

Applicant also argues regarding the 35 U.S.C. §103(a) of claims 13-15, 18, 19 and 24-28 over Arm et al. stating, "Arm does not disclose, teach or suggest an implant having a "varnish-like" coating. Arm discloses "wrapping" such biodegradable films on surgical screws, rods, pins, plates and the like. Arm is silent as to providing a varnish-like coating on an orthopedic implant."

These arguments have been fully considered, but were not found to be persuasive. The term varnish-like is relative in terms that it does not provide sufficient definition as to distinguish over the polymer coatings of the prior art. The prior art teaches that the biodegradable films are useful as coating for prosthetic devices and surgical implants. The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates and the like. Implantable devices of this type are routinely used in orthopedic surgery. The films can also coat bone filling materials, be applied to surfaces of prosthetic devices and can be used to promote tissue ingrowth (page 13, lines 9-21). Therefore, one of ordinary skill in this art would employ biodegradable films in implants such as those disclosed Arm et al. based on the

teachings of the prior art. The burden is shifted to the Applicant to show that the properties imparted by the prior art coatings do not provide for similar properties as those obtained with the varnish-like coating.

With regards to the Applicants argument that "Eitenmuller and Healy do not disclose an implant wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo" is also not persuasive since this limitation is a future intended use that without structural limitation, affords no patentable weight. The prior art recognizes and acknowledges effective biodegradable films employed in orthopedic prosthetic devices and implants. Hence, the instant invention remains unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns H.N.S.
March 29, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600